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ATTORNEY DOCKET NO.: BENDE-004B (formerly BENDE-008B)

SERIAL NO.: 09/733,455

FILING DATE: December 8, 2000

TITLE: Systems for securing sutures, grafts & soft tissue to bone & periosteum

EXAMINER: Michael J. Araj

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Theodore V. Benderev)	Confirmation No.	2632
)		
Serial No.:	09/733,455)	Art Unit:	3731
)		
Filed:	December 8, 2000)	Examiner:	Michael J. Araj
)		
For:	SYSTEMS FOR SECURING)		
	SUTURES, GRAFTS AND SOFT)		
	TISSUE TO BONE AND)		
	PERIOSTEUM)		

RESPONSE TO NON-FINAL OFFICE ACTION & INTERVIEW SUMMARY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following is responsive to the Office Action mailed October 2, 2006, as well as to summarize the telephonic interview held between the Examiner and the undersigned counsel on October 30, 2006. With respect to the status of the Office Action, it was noted that by virtue of Applicants' Request for Continued Examination under 37 CFR § 1.114, the finality of the previous Office Action had been withdrawn. Accordingly, the present status of the Office Action mailed October 2, 2006 is believed to be non-final.

As for the substance of the Office Action, it was asserted that Applicants' amendment filed July 25, 2006 was objected to under 35 U.S.C. § 132(a) as allegedly introducing new matter into the disclosure, namely, that the Applicants' sling was "permanently implanted." With respect to the prior art, Claims 19, 20, 35, 43, 44 and 49-52 were rejected under 35 U.S.C. 103(a) as being unpatentable over Seitzinger (i.e., United States Patent Number 5,362,294) in view of Buncke (i.e., United States Patent Number 5,931,855), and further in view of Towfigh (i.e., DE 32 27 984 A1). No other issues were presented.

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With respect to the objection under 35 U.S.C. § 132(a), it was confirmed during the telephonic interview that the originally filed application did provide support for a permanently implanted sling. As was discussed, support for such disclosure can be found in the Abstract ("such devices are designed and selectively positioned at a target site and remain seated thereat.") and Paragraphs 10, 13, 70-72, 82 ("... the anchoring systems may be formed from a non-absorbable material such that the same remains permanently imbedded within the body."), 91 and 92 of the present application as published. Indeed, the specification extensively discusses the use of the claimed invention for use in suburethral sling procedures, which are well-known in the art to consist of fixtures that are surgically implanted permanently within the body. *See, e.g.*, Paragraph 10 ("the devices of the present invention are particularly well suited for the attachment of one or both of the opposed ends of a suburethral sling for use in suburethral sling surgery ..."), 22-26, 70-72, and Figures 16, 16a. Indeed, the originally-filed disclosure not only teaches the claimed systems and methods as permanent, surgically-implanted fixtures, but that such surgically-implanted fixtures can be manipulated post-operatively, thus clearly suggesting residency within a patient following the surgical procedure. *See, e.g.*, Paragraph 13 ("such embodiment further advantageously allows for post-operative adjustment ...") and 71 ("such design further advantageously permits for the adjustment of the suture line and/or the sling supported thereby not only intra-operatively, but also post-operatively insofar as the suture line 508 can be extended further, for example, in the direction indicated by the letter X, as may be desired to the extent it is necessary to add extra tension to the suture line 508.").

Accordingly, Applicants respectfully submit that the foregoing disclosure clearly teaches the permanent nature of the implantable slings of the present invention. The Examiner's confirmation and acknowledgement of that fact during the telephonic interview of October 30, 2006 is gratefully appreciated.

With respect to the objections maintained in view of the prior art, Applicants respectfully submit that by virtue of the permanent nature by which the implants of the present invention are surgically secured within a patient, as supported by the aforementioned disclosure, the claims as previously presented are novel and non-obvious in view of the cited prior art. To assist the Examiner in establishing this fact, Applicants are incorporating

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portions from the remarks made in the response dated July 25, 2006 wherein the prior art references were distinguished from the claimed invention.

As the Examiner will recall, Applicants have amended dependent Claim 19 to recite a surgical tissue implant including a sling that remains permanently implanted within a patient that is disposed upon an end of at least one suture having a plurality of anchor members disposed linearly thereupon and operative to penetrate into and become imbedded within soft tissue at a selected target sight such that the sling remains in permanent orientation relative the internal organ or tissue that the sling is adjacent.

Similarly, Applicants have further amended independent Claim 35, directed to a method for providing permanent support to an internal organ or tissue that recites the step of providing an implant having a sling disposed between the proximal ends or first and second suture lines, the latter having a plurality of anchor mechanisms disposed linearly thereupon, respectively, where each one of the anchor members is operative to penetrate into and become embedded (fixed in position) within the target sight of soft tissue, and introducing such implant within a patient's body such that the sling is permanently positioned adjacent to said internal organ or tissue and the suture lines advanced through dedicated target sights of soft tissue and become imbedded within soft tissue at said target sights such that the sling is maintained in a fixed position and orientation relative the internal organ or tissue.

As amended, independent Claims 19 and 35 are clearly novel and non-obvious over the prior art. Indeed, not only do the prior art references fail to teach or suggest the present invention as claimed, such references actually teach away from the claimed invention. Indeed, if these references were somehow modified to derive the present invention, would render at least the primary reference, namely, Seitzinger, completely inoperable for its intended purpose. In this regard, it should be appreciated that the present invention is directed to surgical implants and methods of providing support to organs and tissue that provide for a sling that is permanently implanted in fixed position relative an organ or tissue to thus provide permanent post-operative support to such anatomical structures. See, e.g., Application at page 11, lines 8-19; and page 25, lines 4-11. Indeed, implants of the present invention are particularly intended for use in providing long-term urethral support for the

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treatment of incontinence. See Application, page 23, lines 23-32; page 24, lines 16-20; Figure 16 and 16a.

The Seitzinger reference, in contrast, discloses a sling for retracting a body organ during a laparoscopic surgical operation. Such sling is neither intended nor adapted to ever be used as a permanent surgical attachment, but rather is to be removed from the body following the laparoscopic surgical procedure. See, column 2, lines 4-8 (“when the operation is complete ... the sling [is] removed from the organ which returns to its normal position. The sling is next withdrawn through the cannula ...”; column 3, lines 26-29; and Abstract. Accordingly, the Seitzinger reference is limited exclusively to temporary use of slings that are to be deployed only during laparoscopic procedures and are not to be permanently implanted.

However, with respect to the use of the slings disclosed in Seitzinger, such slings are meant to retract a body organ so that it does not interfere with the surgical procedure. Column 1, lines 30-32 and 50-53; Column 2, lines 20-22; Abstract. Sutures on opposed ends of the sling extend through the patient’s abdominal wall and clamped outside of the body. Column 3, lines 7-20; Figure 3 (note specific reference to clamp 26). Indeed, such teachings enable the surgeon to “easily change the position” of the organ during the surgical procedure. Column 3, lines 18-20.

The ability to easily change the position of an organ during surgery could not be accomplished by using the one-way sutures and anchors of Buncke and Towfig. As will be easily appreciated, Buncke and Towfig teach uni-directional suture and anchoring devices and, if used with the slings disclosed in Seitzinger, could only be used to raise or lift an organ and would not enable the surgeon to “easily change the position” of the organ as is taught by the Seitzinger reference. Indeed, even assuming for sake of argument that the one-way suture and anchor of Buncke and Towfig were used with the sling of Seitzinger, to the extent a surgeon were to pull too much on the sling via such sutures and anchors, the surgeon would have no alternative but to cut the suture with anchors from the sling, pull the cut suture from the body, laparoscopically introduce another one-way suture with anchors, tie the same to the sling, and again advance such suture with anchors through the abdominal wall to “try again.”

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Such an approach would be completely impractical and would substantially increase the complexity, duration, and trauma associated with such a surgical procedure.

As should be appreciated, prior art references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02 VI. In this case, when taken as a whole, it is clear that the cited references are incompatible with one another and do not teach or suggest Applicants' invention.

Moreover, even assuming that the aforementioned references could be combined or modified does not render the combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F2d 680, 16 USPQ 2d 1430 (Fed. Cir. 1990); MPEP § 2143.01 III. It is likewise particularly inappropriate to combine references where the references teach away from their combination. In re Grasselli, 713 F2d 731, 743, 218 USPQ 769, 779 (Fed. Cir. 1983); MPEP § 2145. It is further well understood that any proposed modification that would render the prior art inoperable for its intended purpose is inappropriate in maintaining an obviousness rejection. In re Gordon, 733 F2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984); MPEP § 2143.01 V.

Applicants respectfully submit that each of the foregoing bases applies with respect to the rejection being maintained in the Office Action and, in light of the amendments previously made to the currently pending claims, any rejection maintained under 35 U.S.C. § 103(a) in view of the combination of the Seitzinger, Buncke and Towfig references, either alone or in combination, cannot properly be maintained. Applicants therefore respectfully request that such rejection be withdrawn.

With respect to any remaining issues that may exist, and in particular with respect to potential concerns of the Examiner regarding the current claim language of the claims as currently pending, Applicants submit that the claims as written are in condition for immediate allowance. To the extent the Examiner has any suggestions to more clearly define the subject matter of the present invention, Applicants would like to express their willingness to discuss any claim language proposals that the Examiner may have. To that end, the Examiner's assistance is gratefully appreciated.

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To the extent the Examiner has any questions, requires additional information and/or has any suggestions to resolve any outstanding issues that may exist, the Examiner is invited to contact Applicants' counsel at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 11/2/06

By: 

Customer No.: 007663

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